

REMARKS

The application has been amended. Claims 1-5, 9-13, and 15-18 are currently pending. Reconsideration is respectfully requested.

REJECTIONS UNDER 35 U.S.C. §112

The Examiner has rejected claims 16 and 18 under 35 U.S.C. §112, first paragraph, as containing subjection which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More specifically, the Examiner states:

It appears that second body 7 (figure 2) and second body 10 (figure 3) extend only partially in the circumferential direction since they are termed "strips" in the specification. Yet, the second bodies (e.g. second bodies 7 and 10) are referred to as a tubular bodies throughout the specification. Thus, it is unclear from the disclosure if second bodies 7 and 10 are tubular bodies which extend completely 360 degrees circumferentially or not. In other words, it is unclear if each of the three rectangular blocks on the right side of figure 2 represents a tubular body which extends completely 360 degrees circumferentially or not.

The rejection is respectfully traversed. Claim 16 as currently standing provides for a first perimetricaly non-continuous polytetrafluoroethylene tubular inner body and a second perimetricaly non-continuous polytetrafluoroethylene outer tubular body. Applicants have provided clarifying comments regarding these terms in response to the last Office Action. See page 3 of Response dated December 19, 2002.

By way of further explanation, however, Applicants point to the specification on page 7, lines 19-22 where Applicants define the term non-continuous as a tubular body which is not substantially uninterrupted along its length. The phrase "perimetricaly non-continuous" therefore refers to a tubular structure which is non-continuous along its circumference throughout the length of the tubular body.

Applicants further point out that the same language used in claim 16 has been used in claim 1 to describe the second perimetricaly non-continuous tubular body. As the Examiner has determined that claim 1 satisfies the requirements with regard to 35 U.S.C. §112, first paragraph, claims 16 and 18 should also meet these requirements.

The Examiner further refers to second body 7 of Figure 2 and second body 10 of Figure 3 with regards to claims 16 and 18. Applicants point out that claims 16 and 18 are not necessarily limited to the embodiments shown in Figures 2 and 3. This may be one embodiment of the present invention, but claims 16 and 18 are not necessarily limited to these embodiments. By way of clarification however, Applicants point out that second bodies 7 and 10 shown in Figures 2 and 3 are longitudinally arranged segments which may be continuous around the entire circumference of the tubular body or may be perimetricaly non-continuous as indicated in the specification.

In view of the above remarks, withdrawal of the rejections and reconsideration are respectfully requested.

REJECTIONS UNDER 35 U.S.C. §103(a)

The Examiner has rejected claims 1-5, 9-13, 15, and 17 under 35 U.S.C. §103(a) as being unpatentable over EP 0893108 to Ray. More specifically, the Examiner states:

Ray shows first substantially continuous PTFE tubular body 4, second perimetricaly non-continuous tubular body (the longitudinally extending strips of the coupling member described in col. 9, lines 13-21) formed of polytetrafluoroethylene (as indicated in col. 16, lines 20-31) and support structure 6. The Ray specification fails to state that axial and radial compliance is provided to the prosthesis. However, it would have been obvious that axial and radial compliance is provided to the prosthesis due to the gaps between the strips. As to claim 3, note col. 7, lines 24-26 which indicate that the coupling member may be located on the inner rather than the outer surface of the stent.

The rejection is respectfully traversed.

In response to Applicants' previous arguments, the Examiner alleges that the reference to "longitudinally extending strips" in col. 9, lines 18-21 of Ray clearly refer to strips that extend along (parallel to) the longitudinal axis of the prosthesis since such strips are "longitudinally extending." The Examiner further alleges that the use of this phrase rather than the term "helical" (which is used to describe other embodiments) indicates that a structure other than helical is intended. Applicants respectfully disagree.

By way of a background, European Patent Application No. 893,108,822 to Ray et al. (hereinafter "Ray") discloses a kink-resistant stent/graft with an ePTFE tube, a stent, and a coupling member. A coupling member in Ray is a ribbon which covers only a portion of at least one of the inner and outer surfaces of the stent and is utilized solely for securing the stent member and graft member to each other. The ribbon coupling member is circumferentially wound around the graft. See Figures 1A, 1B, 1C, 2, 4, 5, 6, 7, and 8 of Ray.

A careful examination of the specification of Ray details the importance of a helical winding of the coupling member, an embodiment which is seen in each of the figures of Ray. See, e.g., column 7, line 50-column 9, line 12, where Ray continually refers to the advantages of using a helically wound coupling member.

The present invention provides a second tubular body formed of elongate polytetrafluoroethylene strips arranged longitudinally in a non-overlapping relationship. Even if the Examiner's allegation that the longitudinally extending strips of Ray are longitudinally arranged with regard to the tubular body is accurate, it is not specified in Ray whether the strips are non-overlapping. This is further not taught or suggested anywhere in Ray's disclosure nor is it alleged by the Examiner that it is taught or suggested in Ray.

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Given the importance of a helically wound coupling member in Ray, it would therefore be antithetical to the proposed meaning of Ray to use a non-helical wrap, or longitudinally extending strips non-overlapping as claimed in the present invention. Ray, therefore, fails to render the present invention obvious.

The rejection based on 35 U.S.C. §103(a) is therefore respectively traversed. Withdrawal of the rejection and reconsideration are respectfully requested.

The Examiner has further rejected claims 16 and 18 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,398,803 to Layne et al. (hereinafter "Layne"). More specifically, the Examiner states:

Layne show first perimetricaly non-continuous polytetrafluoroethylene inner tubular body (the inner "lacey" graft described in col. 5, lines 29-42), second perimetricaly non0continuous outer tubular body (the outer "lacey" graft described in col. 5, lines 29-42), support structure 30, both the outer and inner tubular body being formed of strips 48. The Layne et al. specification fails to specifically state that axial and radial compliance is provided to the prosthesis. However, it would have been obvious that axial and radial compliance is provided to the prosthesis due to the openings between the strips.

The rejection is respectfully traversed.

The application has been amended to clarify the inventive subject matter. More specifically, claims 16 and 18 have been amended to indicate that the perimetrical non-continuity

of the tubular structure extends over the entire longitudinal length of the tubular bodies. This is clearly not seen in Layne. The "lacey" structure of the tube is constructed by cutting apertures into an ePTFE tube. See Figures 2 and 3 of Layne. The ePTFE tube may also have slits as seen in Figure 4 of Layne. "Strips 48", to which the Examiner refers are not analogous strips at all as they are connected to each other by circumferential sections 46 as seen in Figure 2.

Layne therefore discloses neither a first nor a second perimetricaly non-continuous polytetrafluoroethylene inner tubular body wherein the tubular body is non-continuous along the entire length of the tubular body. Still further this is neither taught nor suggested in Layne. It is still further not been alleged by the Examiner that it is taught or suggested by Layne.

It would not be an obvious addition to Layne to provide a perimetricaly non-continuous tubular body as presently claimed. It is stated in the summary of the invention that Layne is designed to provide an encapsulated stent wherein flexibility of the stent is retained despite encapsulation. See summary, column 1, lines 63-67 of Layne. It would therefore be contrary to the proposed disclosure of Layne to provide a perimetricaly non-continuous tubular body as claimed in the present invention. Such a perimetricaly non-continuous tubular body does not provide an encapsulated stent as the stent is not wholly encapsulated by such a tubular body as it is in the embodiments of Layne.

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The rejection based on 35 U.S.C. §103(a) is therefore respectfully traversed. Withdrawal of the rejection and reconsideration are respectfully requested.

Should the Examiner have any questions or comments concerning this application or this amendment, he is invited to contact the undersigned counsel.

Respectfully submitted,



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VERSION OF AMENDMENTS WITH MARKINGS
SHOWING CHANGES MADE

IN THE CLAIMS:

16. (Amended) An implantable composite intraluminal prosthesis comprising:
a first perimetrically non-continuous polytetrafluoroethylene tubular inner body;
a second perimetrically non-continuous polytetrafluoroethylene outer tubular body; and
a circumferentially deformable support structure interposed between the inner and outer
tubular bodies, both said outer tubular body and said inner tubular body being formed of
polytetrafluoroethylene strips, having a longitudinal length greater than its width, and said strips
within each tubular body arranged in non-overlapping relationship, with the strips of the inner
tubular body overlapping the discontinuities of the outer tubular body, and secured in the
overlap, whereby axial and circumferential compliance is provided to said prosthesis, wherein
both said first inner tubular body and said second outer tubular body are non-continuous along
the entire length of said tubular bodies.

18. (Amended) A method of providing axial and circumferential compliance to an
intraluminal prosthesis stent/graft composite comprising:

- a) positioning PTFE strip components, having a length greater than their width,
lengthwise along a mandrel, in non-overlapping relationship, to form a
circumferentially non-continuous polytetrafluoroethylene tubular first body;
- b) positioning a deformable support structure over said first body;
- c) positioning PTFE strip components, lengthwise along the longitudinal axis of said
inner body, in non-overlapping relationship but overlapping the discontinuities of
the first body to form a second body; and

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d) securing said second body to the first body to form said prosthesis, wherein said inner tubular body and said second body are non-continuous along the entire longitudinal length of said tubular bodies.